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Effectiveness of cognitive behavior treatment for pediatric obsessive-compulsive disorder: Acute outcomes from the Nordic Long-term OCD Treatment Study (NordLOTS)

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ABSTRACT

Objective: The purpose of this study was to examine the acute effectiveness of manualized exposure-based CBT with a family-based treatment, as an initial treatment for pediatric OCD delivered in regular community child and adolescents outpatient clinics. The report summarizes outcome of the first treatment step in the NordLOTS, which was conducted in Denmark, Sweden and Norway.
Method: 269 participants, age 7–17, with OCD, received treatment for 14 weekly sessions. Treatment response was defined as CY-BOCS score of ≤15 at post treatment.
Results: 241 participants (89.6%) completed all 14 weeks of treatment. Treatment response among the completers was 72.6% (95% CI 66.7%–77.9%). Mixed effects model revealed a statistically significant effect of time $F(1,479) = 130.434$. Mean symptom reduction on the CY-BOCS was 52.9% (SD = 30.9). The estimated within-group effect size between baseline and post treatment was 1.58 (95% CI: 1.37–1.80).
Conclusion: This study found that manualized CBT can be applied effectively in community mental health clinics. These findings underscore the feasibility of implementing exposure-based CBT for pediatric OCD in a regular child and adolescent mental health setting.
Clinical trials registration information: This study was registered in Current Controlled Trials; Nordic Long-term Obsessive-compulsive disorder (OCD) Treatment Study (www.controlled-trials.com ISRCTN66385119).

Is it possible to conduct effective treatment for pediatric obsessive-compulsive disorder (OCD) in regular community child and adolescents outpatient clinics? As demonstrated in many open and randomized controlled trials (RCTs), exposure-based cognitive behavioral therapy (CBT) is an efficacious treatment for children and adolescents with OCD. These trials were conducted primarily in university-based clinics, and thus the generalizability of their findings needs to be established in regular community settings.

OCD is characterized by recurrent obsessions and compulsions. Symptoms of OCD in youth are diverse and largely convergent with symptom profiles seen in adults (Bloch, Landeros-Weisenberger, Rosario, Pittenger, & Leckman, 2008). Prevalence studies estimate that between 0.5% and 3% of children and adolescents suffer from OCD (Heyman et al., 2003; Leonard et al., 1993), childhood or adolescent onset is seen in up to 50% of adult cases (Geller et al., 1998; Nelson & Rice, 1997; Riddle, 1998; Taylor, Asmundson, & Jang, 2011).

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OCD often causes a high degree of distress and impaired functioning, with a fluctuating course and high risk of chronic outcomes (Piacentini, Bergman, Keller, & McCracken, 2003; Thomsen, 2000). OCD related impairment interferes with the child's daily functioning (family, social and academic performance), and may have an adverse impact on the child's psychosocial development (Peris et al., 2008; Piacentini et al., 2003; Storch et al., 2007; Valderhaug & Ivarsson, 2005).

Controlled clinical trials with young people diagnosed with OCD support the efficacy of CBT as well as medication with serotonin reuptake inhibitors (SRI) (Abramowitz, Whiteside, & Deacon, 2005; Geller, Biederman, Stewart, Mullin, Martin, et al., 2003; Watson & Rees, 2008). International expert guidelines recommend the use of exposure-based CBT as a first-line of treatment for children and adolescents with OCD (NICE, 2005) and SRI or combined treatment (CBT plus SRI) for moderate to severe OCD (Geller et al., 2012). These recommendations are supported by meta-analyses of randomized controlled trials for pediatric OCD, with between group effect size (ES) estimates of 1.45 (95% CI = 0.68–2.22) for CBT and 0.48 (95% CI = 0.36–0.61) for pharmacotherapy (Abramowitz et al., 2005; Geller, Biederman, Stewart, Mullin, Farrell, et al., 2003; Watson & Rees, 2008). Even though the data are clear and several international guidelines recommend exposure-based CBT as the first line of treatment for pediatric OCD, few patients actually receive this treatment in child and adolescent mental health clinics (AACAP, 2012; Abramowitz et al., 2005; NICE, 2005; Watson & Rees, 2008). Evaluating the effectiveness of exposure-based CBT outside the context of carefully controlled clinical trials represents an important next step in promoting the use of this efficacious treatment in a wider variety of clinical settings.

The Nordic Long-term OCD Treatment Study (NordLOTS) is a clinical trial based on a stepped-care treatment model, conducted in three Scandinavian countries (Denmark, Norway and Sweden). The treatment components evaluated in NordLOTS (CBT and SRI) were those with the strongest evidence base (Geller et al., 2012; NICE, 2005). The purpose of The NordLOTS study was: (1) to examine treatment outcome of exposure-based CBT in community mental health clinics (first step), (2) to identify CBT non-responders; (3) to investigate whether an increased number of CBT sessions or medication offered non-responders would yield the best outcome (second step), and (4) to study the long-term durability of treatment by following patients over three years post treatment.

The current paper addresses the first aim (point number one) examining outcome of exposure-based CBT in community settings. Second step treatment outcome will be discussed elsewhere, and data collection for follow-up is ongoing. Overall rationale and details of the entire NordLOTS design have been described elsewhere (Ivarsson et al., 2010; Thomsen et al., 2013).

Effectiveness trials aim to determine whether treatments are efficacious in natural settings and intend to measure beneficial effects across a more heterogenous population (i.e., more comorbidities and more diverse treatment history), thus being closer to "real word settings" (Godwin et al., 2003). One of the main issues in evidence based practice (EBP) is the extent to which results from RCTs can be generalized to community mental health clinics, and to patients being treated in such clinics.

The efficacy of exposure-based (CBT) has been clearly established, and the groundwork which has been laid with respect to examining exposure-based CBT effectiveness, is summarized in Table 1. This study sets the stage for a broader examination of exposure-based CBT, the transportability to the very setting in which most OCD patients receive clinical services. We argue that the transportability of efficacy-validated treatments to community mental health clinics is an important empirical question that warrants answers driven by data.

Table 1
The Mean, SD and effect size of pediatric OCD studies.

Studies	CY-BOCS pre	CY-BOCS post	SD pre	SD post	Sample size	ES
Barrett (2004)	21.4	8.4	5.6	6.9	22	1.66
Freeman (2014)	26.0	12.3	4.0	5.4	63	2.32
Piacentini (2011)	24.7	13.3	4.7	8.2	49	1.41
POTS (2004)	26.0	14.0	4.6	9.5	28	1.35
Reynolds (2013)	24.3	14.3	4.6	8.6	25	1.21
Storch (2013)	25.1	16.4	4.0	8.6	31	1.10

The aim of the present paper was to examine the effectiveness of exposure-based CBT for pediatric OCD patients in community mental health setting. We hypothesized that exposure-based CBT delivered in community mental health clinics would be effectively and feasibly delivered, resulting in a significant change in CY-BOCS total score from pre to post-treatment, with an effect size approaching those reported in efficacy studies.

Methods

Study design

NordLOTS is based on a stepped-care treatment model. The first step was an open uncontrolled clinical trial, with fourteen sessions of exposure-based CBT to all participants. Assessment points were at baseline, weeks 7 and 14 (post treatment), assessed by independent evaluators (IEs) using the Children Yale-Brown Obsessive Compulsive Scale (CY-BOCS). The CY-BOCS is a clinician-rated instrument that combines data from clinical observations, and child and parent reports, CY-BOCS assess obsessions and compulsions separately. As the primary scalar outcome variable, the CY-BOCS total score provides an indication of the degree of change (see Measures).

Clinics

Clinics participating in NordLOTS were public community mental health clinics, with general referrals, that serve children and adolescents 18 years or younger with a range of emotional and behavioral problems. The community mental health services are a part of the general national health services, provided free of charge. All the NordLOTS clinics were similar in terms of their organization, referral procedures and service provided, with the exception that the therapists at the OCD clinics (Aarhus and Gothenburg) mostly treated patients with OCD.

Five main study sites participated: (1) The OCD-clinic, Regional Center for Child and Adolescent Psychiatry, Risskov, Aarhus University Hospital, Denmark, (2) The Centre for Child and Adolescent Mental Health Eastern and Southern, Oslo, Norway, (3) The Regional Centre for Child and Adolescent Mental Health, Mid-Norway, Trondheim, Norway, (4) BUP Signal in Stockholm, *Sweden*, with an additional 8 other community mental health clinics, and (5) The OCD-clinic, Queen Silvia Children's Hospital, Gothenburg, Sweden (Table 2.).

Therapists

The study-therapists were either psychiatrists, clinical psychologists or certified psychotherapists. Half of the therapists had five to ten years of clinical experience, while the other half had ten years or more. Therapist's prior experience with exposure-based

Table 2
Number of therapist and patients for each site.

Site	Aarhus Denmark	Gothenburg Sweden	Stockholm Sweden	Southern-eastern Norway	Central Norway	Total
Number of patients	80	48	30	41	70	269
Number of clinics at each site	1	1	9	5	4	20
Number of therapist	6	3	12	9	14	44

CBT for pediatric OCD, varied both between and within sites. The therapists at the two OCD clinics had more experience with exposure-based CBT for OCD. At the remaining three sites, which included 18 smaller community mental health clinics, few of the therapists had prior training in exposure-based CBT for OCD. Forty-four therapists provided the exposure-based CBT (Table 2). The number of patients per therapist varied to a large degree both between and within sites. Nine of the forty-four therapists treated more than ten patients, five treated only one patient. One hundred and fifty-one of the patients (56.1%) came from an OCD clinic (Table 3).

Training in exposure-based CBT varied according to the therapist's prior experience treating pediatric OCD. The pre-experience level of CBT treatment at each site was a deciding factor when determining the degree of pre-study therapist training at each site. Leadership at each site decided the necessity and intensity of CBT training prior to the study in an agreement with the PI of the NordLOTS trial. Therapists at sites with little or no prior CBT experience received ten days of training with the NordLOTS treatment manual. They also received monthly group supervision, for three consecutive hours, at their respective sites throughout the study. Experienced doctor-level clinical psychologists and psychiatrists, were responsible for the CBT training and supervision. The therapists at the two OCD clinics studied the NordLOTS manual prior to study start without additional training or supervision.

Participants

Patients were referred from community health centers, general practitioners or parents who contacted the clinics directly. To ensure a representative sample of pediatric patients seeking treatment for OCD, exclusion criteria were kept to a minimum. A total of 767 children and adolescents were screened for participation, 491 met inclusion criteria for assessment, and 269 were included in step 1 (Fig. 1). The mean baseline CY-BOCS total score was 24.6 (SD 5.1), subscale scores for obsession 12.3 (SD 2.8) and compulsion 12.3 (SD 2.7). Child age ranged from 7 to 17 years, mean 12.8 (SD 2.7) years. Genders were equally represented, females 51.3% ($n = 138$). The sample was primarily of Scandinavian ethnicity as 97% ($n = 261$) had either mother, father or both of Scandinavian origin. Almost half (40.5%, $n = 109$) of the patients had one or more comorbid psychiatric disorder (Table 4).

Patients were included into the study if they fulfilled the following criteria: (1) primary diagnosis of OCD in accordance with the criteria in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR) (American Psychiatric Association, 2000), (2) CY-BOCS entry score ≥16, (3) 7–17 years of age, and (4) patients with attention-deficit-hyperactivity disorder (ADHD) were eligible, after having been stabilized on medication for at least 3 months prior to entry. Exclusion criteria included: (1) the presence of other psychiatric disorders (according to the DSM-IV) having a higher treatment priority (i.e., psychosis and severe depression), (2) any specific developmental disorder (i.e., pervasive developmental disorder [PDD] or Asperger's disorder). However, a diagnosis of PDD NOS

Table 3
Number of patient for each therapists.

Number of patients	Number of therapists
1	5
2	10
3	6
4	6
5	5
6	1
7	2
11	3
12	1
14	1
19	1
20	1
23	1
37	1

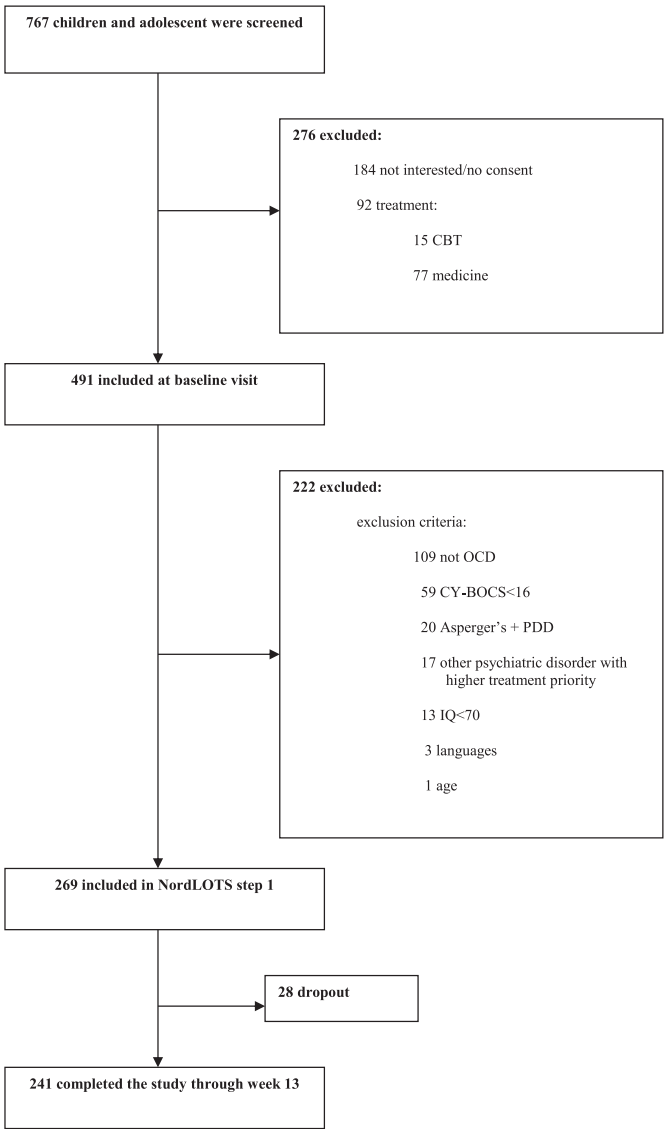

Fig. 1. Flow diagram of the NordLOTS treatment study.

Table 4
Baseline demographic and clinical characteristics and observed cases by time point.

Variable	Total	Aarhus OCD clinic	Gothen. OCD clinic	Stockh.	East/South Norway	Central Norway	*p*-value
Age, mean (SD)	12.8 (2.7)	12.5 (2.7)	13.0 (2.4)	12.9 (2.8)	14 (2.5)	12.3 (12.3)	.024
Sex N (%)							
Male	131 (48.7)	32 (40)	21 (43.8)	9 (30.0)	30 (73.2)	39 (55.7)	.001
Female	138 (51.3)	48 (60)	27 (56.3)	21 (70.0)	11 (26.8)	31 (44.3)	
Family status							
Parents living together	174 (64.7)	51 (63.7)	30 (62.5)	24 (80.0)	26 (63.4)	43 (61.4)	.102
Divorced	91 (33.8)	25 (31.3)	18 (37.5)	6 (20.0)	15 (36.6)	27 (38.6)	
Other	4 (1.5)	4 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
SES							
Major/medium business and major/minor professional	140 (53.4)	34 (43.0)	26 (54.2)	19 (63.3)	32 (78.0)	29 (45.3)	.003
Skilled craftsmen to unskilled laborers	122 (46.6)	45 (57.0)	22 (45.8)	11 (36.7)	9 (22.0)	35 (54.7)	
Ethnicity							
Scandinavian children (Mother or father Scandinavian)	261 (97)	80 (100)	44 (91.7)	27 (90.0)	40 (97.6)	70 (100)	
CY-BOCS (Scalar variables, mean (SD))							
Total baseline	24.6 (5.1)	24.4 (5.3)	24.3 (4.1)	23.0 (5.1)	26.2 (4.7)	24.9 (5.5)	.061
Baseline obsessions	12.3 (2.8)	12.2 (2.8)	12.1 (2.2)	11.4 (3.0)	13.3 (2.4)	12.3 (3.1)	
Baseline compulsions	12.3 (2.7)	12.2 (2.9)	12.2 (2.2)	11.6 (2.5)	12.9 (2.6)	12.5 (2.8)	
Baseline comorbid disorders (K-SADS-PL)							
Anxiety disorders	52 (19.3)	13 (16.7)	16 (33.3)	5 (19.2)	4 (9.8)	14 (20.0)	.071
Depressive disorders	10 (3.7)	0 (0.0)	6 (12.5)	0 (0.0)	3 (7.3)	1 (1.4)	.002
ADHD	24 (8.9)	2 (2.6)	9 (18.8)	0 (0.0)	9 (0.0)	13 (18.6)	.001
ODD/CD	10 (3.7)	1 (1.3)	4 (8.3)	0 (0.0)	1 (2.4)	4 (5.7)	.200
Tic	49 (18.6)	5 (6.4)	20 (41.7)	1 (3.8)	2 (4.90)	21 (30.0)	.001
Number of co-occurring diagnoses							
None	160 (59.5)	57 (75.0)	12 (25.5)	20 (76.9)	32 (78.0)	38 (54.3)	.001
One	62 (23.0)	17 (22.4)	18 (38.3)	4 (15.4)	8 (19.5)	16 (22.9)	
Two	23 (8.6)	1 (1.3)	11 (23.4)	1 (3.8)	1 (2.4)	9 (12.9)	
Three or more	15 (5.6)	1 (1.3)	6 (12.8)	1 (3.8)	0 (0.0)	7 (10.0)	

Note: SES = Socioeconomic Status; CY-BOCS = Children's Yale-Brown Obsessive Compulsive Scale; K-SADS-PL = Schedule for Affective Disorders and Schizophrenia for School-Age Children – Present and Lifetime version; ADHD = Attention Deficit Hyperactive Disorder; ODD/CD = Oppositional Defiant Disorder/Conduct Disorder.

was allowed as long as OCD was judged to be the primary disorder based on the respective Clinical Global Impression-Severity (CGI) scores, (3) a previous failed trial of exposure-based CBT for OCD within less than 6 months prior to inclusion, (4) medication treatment with an SRI less than 6 months prior to inclusion, and (5) inadequate language proficiency by the patient or the parent.

Treatment

The exposure-based CBT treatment manual was based on the study protocol designed by March and Mulle in collaboration with Foa and Kozak (March, Mulle, Foa, & Kozak, 2000). The manual was modified by adding more extensive family participation based on the work of Piacentini, Langley, and Roblek (2007). The NordLOTS exposure-based CBT regime consisted of 75 min weekly sessions for 14 weeks. Parents were expected to accompany their children to all sessions. The children were seen together with their parents in six of the fourteen sessions (sessions 1–3, 5, 11, and 14). In the remaining sessions, the child was treated individually for 45 min and then the parents were seen with or without the child for an additional 30 min. This extra time was added specifically to address issues regarding the parents' involvement in therapy, and their attitude and feelings about their child's OCD symptoms.

In sessions one to three, the main focus was on psychoeducation, explaining the OCD and the treatment, including detailed explanation of exposure and response prevention (E/RP). Furthermore, the sessions included efforts to develop a symptom hierarchy, formulate a treatment plan, and externalize the OCD. E/RP exercises were initiated in session three and conducted in each subsequent treatment session. The focus of the treatment was a gradual exposure to threatening situations based on a detailed symptom hierarchy, with the goal to reach the top of the hierarchy. Homework exposure exercises were an essential part of the treatment, parents were asked to support and monitor homework assignments, at least for younger children. Towards the end of the therapy, the emphasis shifted to generalizing skills and relapse prevention.

Independent evaluation

IEs were experienced clinical psychologists and psychiatrists from each of the three countries. All IEs were trained in the use of the Schedule for Affective Disorders and Schizophrenia for School-Age Children – Present and Lifetime version (K-SADS-PL) and the CY-BOCS via formalized training procedures from a doctor-level psychiatrist (the PI for the NordLOTS). The training was based on observing and coding both taped and live K-SADS-PL and the CY-BOCS interviews. Assessments were audiotaped; the same IEs performed the assessment at baseline (K-SADS-PL and the CY-BOCS), and at week 7 and post treatment (CY-BOCS). A random sample of 30 audiotapes of baseline CY-BOCS interviews, out of a possible 269 (11.2%), were evaluated by quality assurance (QA) raters. The QA raters had extensive experience and expertise in the use of the CY-BOCS. The analysis revealed that the intraclass correlation coefficient (ICC) was 0.94 (95% CI 0.85–0.97) for obsessions, 0.87 (95% CI 0.67–0.93) for compulsions and 0.92 (95% CI 0.78–0.97) for the total score. No reliability test was performed for the K-SADS-PL.

All the therapy sessions were audiotaped and a random sample of 280 (12.8%) treatment sessions out of a total of 2184 available sessions were scored by the QA's for treatment fidelity and therapist competences all therapists were rated at least one time. The randomly chosen sessions were evenly distributed across the 14 treatment sessions with at least one session from each patient. The NordLOTS Treatment Integrity Scale (TIS) was used for determining treatment fidelity. The TIS was developed by the NordLOTS research

group, and was largely based on the CBT-QA (quality assessment) form used in the POTS study (2004). Three categories of treatment fidelity were evaluated: (1) manual adherence, (2) competence in manual delivery, and (3) therapist relational competencies. Scores in each of these categories ranged from 1 = very poor compliance to 4 = very good compliance. All of the sessions were rated "good" or "very good", for overall manual adherence 94.7% (95% CI 91.4–96.8%), manual competence 96.0% (95% CI 93.0–97.7%), and relational competencies 96.0% (95% CI 93.3–97.7%). For additional information of this procedure, see Thomsen et al., 2013.

Measures

The following instruments were used as measures for inclusion, and/or measures of treatment outcome:

Schedule for Affective Disorders and Schizophrenia for School-Age Children – Present and Lifetime version (K-SADS-PL) (Kaufman, Birmaher, Brent, & Rao, 1997). The K-SADS-PL is a semi-structured diagnostic interview that assesses a range of child psychopathology. The K-SADS-PL has good psychometric properties with an interrater reliability of 98% and a 1–5 week test-retest kappa of 0.80 for any anxiety disorder diagnosis (Kaufman et al., 1997). Both convergent and divergent validity have been documented in a Nordic sample of adolescents (Lauth et al., 2010). Symptoms can be classified as "not present", "possible", "in remission", or "certain". In this study, OCD diagnoses and comorbidity were based on symptoms classified as certain only.

Children Yale-Brown Obsessive Compulsive Scale (CY-BOCS) (Scahill, Riddle, McSwiggin-Hardin, & Ort, 1997). The CY-BOCS is a widely used, clinician-rated, semi-structured interview assessing the severity of OCD symptomatology. The CY-BOCS evaluates the severity of obsessions and compulsions, using10 items, across five dimensions (time occupied by symptoms, interference, distress, resistance and degree of control over symptoms). CY-BOCS shows reasonable reliability and validity (Gallant et al., 2008; Scahill et al., 1997; Storch et al., 2004). Good to excellent inter-rater agreement with kappas of 0.91, 0.68 and 0.84 for obsessions, compulsions and total score, respectively (Scahill et al., 1997). In the NordLOTS sample, the inter-rater agreement with kappas of 0.94 (95% CI 0.85–0.97), for obsessions 0.87 (95% CI 0.67–0.93) for compulsions, and 0.92 (95% CI 0.78–0.97) for total score.

Diagnostic, primary outcome and treatment response measures

Diagnostic status and comorbidity were assessed with the K-SADS-PL (Kaufman et al., 1997), and OCD symptom severity was assessed with the CY-BOCS (Scahill et al., 1997). The primary binary indicator of treatment response was defined as CY-BOCS total score of ≤15, which corresponds to low to mild symptom severity levels. Secondary outcome measures included: (1) clinical remission, which was defined as post treatment CY-BOCS total score of ≤10 indicating a more complete reduction of symptoms (Franklin et al., 2011; Piacentini et al., 2011; POTS Treatment Study Team, 2004), (2) 30% reduction or more on the CY-BOCS total score (Storch, Lewin, De Nadai, & Murphy, 2010; Tolin, Abramowitz, & Diefenbach, 2005), and (3) clinically significant change and reliable change indexes were also calculated according to the formulas reported in Jacobson and Truax (1991). Clinical significant change was defined as, criteria C in Jacobson and Truax (1991); the level of functioning subsequent to therapy should fall outside the range of the general dysfunctional population, when that range is defined as extending to two standard deviations of the mean of the population. Reliable change was calculated using the formula CY-BOCS total pre-test mean subtracted from the post-test mean, divided by the standard error of difference of the two scores (Jacobson & Truax, 1991).

Data handling and statistical methods

The NordLOTS was registered in Current Controlled Trials (www.controlled-trials.com ISRCTN66385119). The Centre for Child and Adolescent Mental Health, Eastern and Southern Norway (RBUP), was the main coordinating site. The database was built using RBUP's data collection infrastructure program (Confirmit Horizons, version 17.0) on a secure research network. In addition to collecting and monitoring data, the database provided flow of patient information throughout the study. All analyses were conducted using intent-to-treat (ITT) principles.

Statistical analyses on the scalar CY-BOCS was conducted using a linear mixed-effects model (Fitzmaurice, Laird, & Ware, 2011; Gueorguieva & Krystal, 2004). Fixed effects were time (baseline, week 7 and week 14), site, and the (time × site) interaction. In all models, random effects included intercept and linear slope terms. An unstructured covariance was used in order to account for within patient correlation across time. Clinical response was analyzed using Generalized Estimating Equations (GEE). When assuming that data are missing at random, GEE models handle missing data on the outcome as effectively as multiple imputations[1] (Twisk & de Vente, 2002; Ziegler & Vens, 2010). In the GEE models, time was treated as a dichotomous variable (week 7 and 14). Study site and (time × site) interactions were also included in the model.

Secondary outcome measures, clinical remission and 30% reduction were analyzed by GEE in a similar fashion as the dichotomous primary outcome. All analyses were conducted in the R statistical program (R Development Core Team, 2008), with packages nlme for mixed effects and gee for GEE analysis. The syntax is available upon request from the corresponding author.

Results

Of all 269 patients, 241 (89.6%) completed the entire 14 weeks of treatment (Fig. 1). Attrition by week 7 was 7.8% (n = 21), total attrition rate by week 14 was 10.4% (n = 28).

Primary outcomes

The ITT linear-mixed effects model estimated mean and standard errors of CY-BOCS total scores by site are presented in Table 5. The mixed effects model of the longitudinal total CY-BOCS score revealed a significant linear effect of time (F[1, 479] = 130.434, p < .001) and time × site interaction (F[8, 479] = 2.557, p < .01). The site effect at baseline was not significant (F[4, 264] = 1.195, p > .05). To assess treatment outcome differences by site, post-hoc pairwise contrasts for the CY-BOCS total score at week 7 and post treatment were conducted. There were significant differences between site, at week 7 (F[4, 264] = 2.594, p = .037). Additional, pairwise post-hoc analysis between the five sites revealed that Aarhus site proved superior to Southern and Eastern Norway (p = .016), Central Norway (p = .009), and Gothenburg (p = .021) sites, in getting early responders. Notably, the post treatment outcomes, analysis did not yield a significant differences between sites in the overall model (F[4, 264] = 0.767, p = .548) (Fig. 2).

Mean CY-BOCS total score symptom reduction from baseline to post treatment was 52.9% (SD = 30.9). Mean CY-BOCS obsession subscale symptom reduction was 51.7% (SD = 33.6) and mean compulsion subscale symptom reduction was 53.6% (SD = 32.1). A paired t-tests (t[240] = 1.5210, p = .132) did not reveal significant differences between the CY-BOCS subscale post treatment.

[1] The analyses in this study were based on completers, the analyses were also done with multiple imputations (MI), with almost identical results.

Table 5
CY-BOCS scalar estimated total mean scores (SE).

Week	Total $n = 269$	Aarhus Denmark $n = 80$	Gothenburg Sweden $n = 40$	Stockholm Sweden $n = 30$	Southern-eastern Norway $n = 41$	Central Norway $n = 70$
0	24.6 (0.40)	24.4 (0.72)	24.3 (0.93)	23.0 (1.18)	26.2 (1.01)	24.9 (0.77)
7	16.4 (0.45)	15.4 (0.81)	18.3 (1.00)	17.1 (1.25)	18.5 (1.03)	18.3 (0.78)
14	11.4 (0.41)	11.6 (0.75)	11.5 (1.01)	11.5 (1.27)	9.8 (1.10)	12.1 (0.80)

Furthermore, the within-group uncontrolled effect size (adjusted for the fact that the two means were not independent) was 1.58 (95% CI: 1.37–1.80) (Morris & DeShon, 2002). Treatment response (based on CY-BOCS total score of ≤15) was 72.6%, (95% CI 66.7–77.9%: $n = 175$). Treatment response rate increased significantly from week 7 (38.3% [95% CI 32.4%–44.5%, $n = 95$]).

Secondary outcomes

CY-BOCS total score was also dichotomized at ≤10 indicating clinical remission. Post treatment 49.4% (95% CI 43.1%–55.6%: $n = 119$), were rated as clinical remitters. The rate of clinical remission increased significantly from week 7 (13.7%, [95% CI 10.0%–18.6%, $n = 34$]). The percentage of participants who experienced a 30% reduction or more post treatment in the CY-BOCS total score was 77.2%, ($n = 186$). This was also a significant increase from week 7 (42.3%, [95% CI 36.4%–48.6% $n = 105$]). Based on the criteria by Jacobson and Truax (1991), 69% (164) of the patients evidenced clinically significant change post treatment on the CY-BOCS. This was corresponding with 70.1% (169) clinical reliable change post-treatment, (CY-BOCS < 15). This was corresponding with 70.1% (169) clinical reliable change on the CY-BOCS from pre- to post-treatment (8 points or more on the CY-BOCS). By pooling these indices, 53.5% ($n = 144$) of the participants achieved both clinically significant change and clinical reliable change.

Discussion

The NordLOTS was conducted in three Scandinavian countries, at five sites, in 20 regular community child and adolescents outpatient clinics. This study is the largest treatment study of pediatric OCD carried out to date, and also the first multi-national, multi-center treatment study in pediatric OCD. The large sample size in this study is a significant strength: compared to other studies both open trials and RCTs, the current study sample numbers three to four times as many patients (Table 1). Furthermore in NordLOTS, attrition rate was low; nine out of ten patients completed the full treatment protocol. Clinicians successfully guided the vast majority of patients through the time consuming and, at times, uncomfortable aspects of exposure-based treatment. Children and their parents showed a high degree of acceptance and willingness to be treated with exposure-based CBT alone.

This study evaluated the effectiveness of 14 sessions of manual-guided exposure-based CBT, with a family-based approach. The aim was to investigate the effectiveness and transportability of such treatment, in busy ordinary community

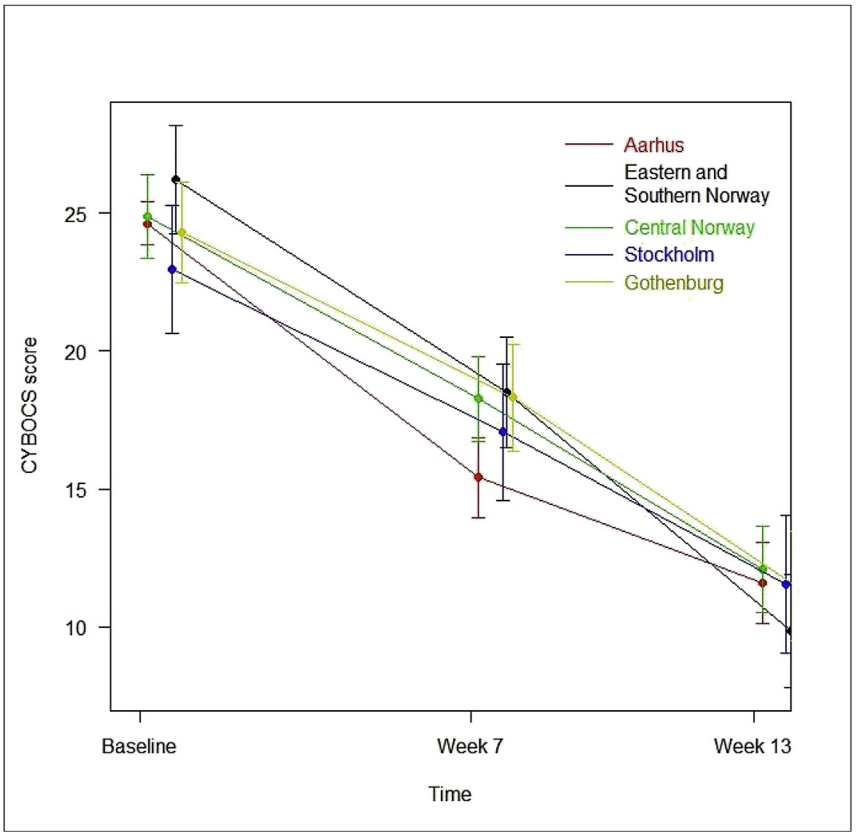

Fig. 2. Weekly adjusted intent-to-treat CY-BOCS total score by treatment site, with 95% CI.

clinics, against outcomes achieved in efficacy studies. Implementation of EBP in community settings is widely debated and demands a close collaboration between clinicians and researchers. One of the major challenges reported by both is the lack of demonstrated success in transporting treatments from the university-based to community settings (Weisz, Weiss, & Donenberg, 1993). The current study offers an important contribution to treatment research in pediatric OCD, by presenting a successful example of transportability of a university developed treatment into community mental health clinics.

In the NordLOTS study, pediatric patients treated with exposure-based CBT, showed a high treatment response, seven out of ten patients were rated as responders by independent evaluators. The results are comparable to several previous open trials conducted at expert sites (Franklin et al., 1998; March, Mulle, & Herbel, 1994; Storch, Lehmkuhl, et al., 2010; Storch, Lewin, et al., 2010). Moreover, due to the broad inclusion criteria and the varied mental health settings in which the trial was conducted, generalizability of the findings in the NordLOTS study to the clinical settings in which most pediatric OCD patients receive care is likely to be high. Our data add evidence for the clinical utility of exposure-based CBT as a first-line treatment for pediatric OCD.

There were no significant site differences at post treatment, despite substantial differences between the various settings (i.e., OCD clinics versus community–based clinics, demographic variations including nationality, urban versus rural catchment areas for sites, clinic size, and comorbidity). The fact that there were no significant differences between the regular outpatient clinics and OCD clinics is especially notable and consistent with previous findings from smaller trials. Exposure-based CBT treatment is effective for pediatric OCD in a wide variety of settings (Bolton & Perrin, 2008; Valderhaug, Larsson, Gotestam, & Piacentini, 2007). The results support the generalizability of the CBT outcome from smaller scale efficacy studies of CBT to community outpatient child and adolescent mental health clinics.

The severity of OCD symptoms decreased significantly over the course of treatment with an observed uncontrolled (adjusted) effect size of 1.58 (95% CI: 1.37–1.80), indicating that CBT treatment is associated with large treatment effect, and absolutely comparable with RCTs (Table 1). The mean CY-BOCS score post treatment was 11.4, which is close to the cut off for clinical remission. Mean symptom reduction in NordLOTS was 52.9%, which is consistent with other studies (Benazon, Ager, & Rosenberg, 2002; March et al., 1994; Wever & Rey, 1997). Nearly half of the patients were defined as being in remission, exceeding the rates reported in most previous studies (Piacentini et al., 2011; POTS Treatment Study Team, 2004).

Another strength of this study was the examination of clinical significant and reliable change. Based on criteria by Jacobson and Truax (1991) 69% ($n = 164/241$) of the patients achieved clinically significant change from baseline to post treatment CY-BOCS, with 70.1% ($n = 169/241$) of the patients meeting criteria for reliable change. These findings indicate that the statistically significant reduction found in this sample, which were comparable to those achieved in expert sites around the world, were also clinically meaningful.

The CY-BOCS, as an outcome measure, has often been reported using either a dichotomization or percentage reduction (Geller, Biederman, Stewart, Mullin, Martin, et al., 2003; Storch, Lehmkuhl, et al., 2010; Storch, Lewin, et al., 2010). In this study, we used clinical response defined as a CY-BOCS score of fifteen or less as our primary outcome measure, and a reduction of thirty percent or more on the CY-BOCS as a secondary outcome. Our definition of clinical response at $\leq$15 on the CY-BOCS total score, might inflate the rate of responders. It is possible, for example, that some patients with a CY-BOCS score just above the cut-off when entering treatment, and a score just below the cut-off for clinical response at week 13 improved due to chance or normal fluctuation of symptoms, rather than as an effect of treatment. There were, however, only 6 patients (2.2%) who were deemed responders (CY-BOCS $\leq$ 15) and who did not obtain 30% or more reduction on the CYBOCS from baseline to post treatment. There was in fact very little difference between the results on treatment response (72.6%), 30% reduction (77.2%) and clinical reliable change (70.1%). Future studies should examine the validity of various response and remission criteria (e.g. convergence with functional improvement) to guide the field regarding the optimal definitions of both.

NordLOTS was not sponsored by industry funding and patients from a variety of regular community child and adolescent outpatient clinics participated. Independent raters were used to assess all outcome measures and therapy adherence and fidelity were excellent. None of the patients in The NordLOTS's primary treatment step received medication for their OCD, which is quite unusual in such a large treatment study. This enables examination of the effects of CBT treatment without introduction of medication confounds. This is also important with regard to patient inclusion. NordLOTS was likely to enroll patients who, because their parents might be against medication use for their children, are unlikely to be enrolled in clinical trials where randomization to medication is a possibility (Benazon et al., 2002).

Limitations

The first step of the NordLOTS was an uncontrolled trial, and the usual threats to internal validity apply here, including the potential effects of time, history, and maturation (Chambless & Hollon, 2012). The degree to which these factors influenced the outcomes cannot be directly determined. However, given the strong and consistent treatment effects observed here, in concert with over a dozen randomized trials worldwide attesting to efficacy of exposure-based CBT for OCD (Barrett, Healy-Farrell, & March, 2004; Bolton et al., 2011; de Haan, Hoogduin, Buitelaar, & Keijsers, 1998; Piacentini et al., 2011; POTS Treatment Study Team, 2004), and a generally low placebo response rate for OCD across many studies and contexts, it seems unlikely that these factors could explain the overall improvement.

The lack of ethnic diversity in the sample, is a limitation. As reported 97% of the patients were of Scandinavian ethnicity and therefore the generalizability to more ethnically diverse countries and clinics is uncertain. However, this problem (i.e., limited ethnic diversity) is highly consistent with the existent OCD literature (Williams, Powers, Yun, & Foa, 2010). Another limitation is that the implementation of the manualized exposure-based CBT with a family-based treatment, the training and supervision of the therapists conducted herein may be difficult to obtain under ordinary or non-research conditions. We argue that similar or at least sufficient conditions comparable to what was done her may also be possible in full-scale implementation. Furthermore, as this treatment has shown to be effective in a large proportion of patients, arguments for cost effectiveness for the whole procedure could easily be derived from this study.

Conclusion

NordLOTS is the largest treatment study for pediatric obsessive-compulsive disorder using cognitive behavior therapy as the initial treatment. This study has demonstrated that manual-guided CBT can be applied effectively in community child and adolescents mental health clinics.

Conflict of interest

We confirm that this manuscript is not under consideration by another journal. All authors have approved the manuscript and agree with its submission to Journal of the BRAT. There is no conflict of interest with any of the authors, which could inappropriately influence this paper. Informed consent was obtained from the patients and their parent after the nature of the study and the procedures was explained. I also confirm that all the individuals listed as authors meet authorship criteria.

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